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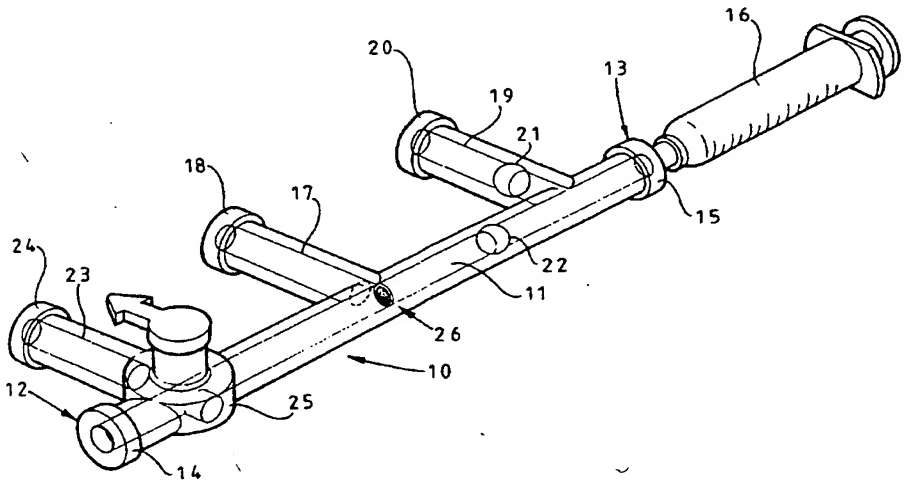

(57) Abstract

A manifold for vascular investigations for example angiograms, in which contrast medium can be injected from a supply (20) using a syringe (16) without the need to manipulate stop cocks on the manifold (10). A non-return valve (21) is provided in the contrast medium supply (20) so that the medium can be drawn into the manifold using a syringe (16) and then injected into the blood vessel. The pressure increase due to injection operates a pressure responsive valve which may either be a non-return valve (22) or a pressure responsive diverter valve (26) to permit injection into the blood vessel while isolating the contrast medium supply (20). The diverter valve (26) isolates a pressure monitoring passageway (17) during injection but is normally biased into a position such that the pressure monitoring valve remains in constant communication with the blood vessel. The manifold operates fully automatically, ensuring that no back flow of blood occurs into the contrast medium supply and ensuring that the pressure monitoring passageway is reconnected after contrast injection has taken place.

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MANIFOLD

This invention relates to a manifold for use in vascular investigations.

It is necessary, during vascular investigations, to maintain monitoring of pressure within the blood vessel being investigated, for example to ensure that no blockage occurs. Additionally it is often necessary to inject fluids such as X-ray contrast media into the vessel.

Other fluids such as blood or saline fluid may be coupled to the blood vessel for continuous or intermittent supply.

To provide means for connection of such fluids to the vessel, a manifold is used, comprising a body having a plurality of input connections of suitable types.

In a typical example, a manifold used for angiograms has a body including a central passageway and two side passages, the one towards the proximal end of the manifold having means for connection of a pressure monitoring line and the one towards the distal end having means for connection of a supply of contrast medium. At the distal end of the manifold is a Luer lock for connection of a syringe. Each of the branches has a three-way stopcock and, during the angiogram procedure, the pressure monitoring line is in communication with the manifold for most of the time. When it is desired to inject contrast medium, it is necessary to close the proximal stopcock on the pressure monitoring line so as to avoid loss of contrast medium into that line and to prevent back flow towards the distal end. The distal stopcock which is normally closed, has then to be opened so that the syringe can be used to draw up contrast medium. Subsequently this is injected through the central passageway and the proximal stopcock is then operated to close off the main passageway from the distal passageway and to re-open the communication between the main passageway

and the pressure monitoring line.

Failure to carry out this procedure correctly can result in failure to provide proper injection of contrast medium or, if the operator forgets to re-open the pressure monitoring line, risk to the patient can occur if there should be any change of pressure within the blood vessel which cannot then be detected.

It is an object of the present invention to provide a manifold which offers advantages over the currently used manifolds.

According to the invention there is provided a manifold including a first passageway adapted to make connection with a blood vessel and a plurality of further passageways which are placed in communication with, or isolated from, the first passageway under the control of at least one pressure responsive non-return valve.

Preferably, the pressure responsive non-return valve comprises a pressure responsive diverter valve having a normal mode and a diversion mode selectively produced in response to a pressure rise in one of said further passageways, the diversion mode causing said one further passageway to communicate with the first passageway and simultaneously to isolate another of the further passageways; return to the normal mode reconnecting said other further passageway and isolating said first further passageway from the first passageway.

The pressure responsive diverter valve may comprise a ball valve moveable between two alternative seats and normally biased into one of said seats.

The biasing may be provided by a perforated membrane obstructing one of said seats.

Alternatively, the diverter valve may comprise a flap valve having two alternative seats and resiliently biased into one of said seats.

In an alternative form of the invention, suitable for use in angiograms, and using non-return valves, the first passageway may be a main passageway having opposite end connections, one of which is adapted to make connection with a blood vessel and two further passageways may be provided, a distal one of which includes one of the pressure responsive non-return valves to prevent back flow into the distal passageway, a further one of the non-return valves being disposed in the main passageway between the proximal and distal secondary side passageways to prevent back flow from the proximal to the distal end of the manifold.

A further secondary side passageway may be provided between the proximal passageway and the distal end of the manifold, this further passageway having a stop cock to permit purging of the manifold before commencement of a procedure.

Embodiments of the invention will now be described in more detail by way of example only with reference to the accompanying drawings in which,

Figure 1 is a diagrammatic side elevational view of a manifold embodying the invention in use,

Figure 2 is a detailed sectional view of part if the manifold of Figure 1,

Figure 3 is a detailed sectional view of an alternative valve arrangement.

Referring to Figure 1 of the drawings, a manifold is generally indicated at 10 and is made as a moulding in synthetic plastics material having sufficient strength and which is

capable of sterilisation, for example polycarbonate resin.

The manifold 10 has a central passageway 11 which extends throughout its length from a proximal end 12 to a distal end 13. Suitable connection means 14 are provided at the proximal end to enable the manifold to be placed in communication with a blood vessel. Connection means 15 at the distal end allow the connection of a syringe 16.

A secondary side passageway 17 is provided which has connection means 18 for connection to a pressure monitoring arrangement such as a pressure monitoring dome of generally known type (not shown). The side passageway 17 generally remains in communication with the central passageway 11 during use of the manifold.

A second side passageway 19, positioned towards the distal end 13 of the manifold 10 is connected by means of a suitable connector 20 to a supply of X-ray contrast medium or other fluid to be injected into the blood vessel. The passageway 19 is provided with a non-return valve 21 which permits fluid to pass from the passageway 19 into the main passageway 11 but does not permit return of fluid. In this way, the X-ray contrast fluid cannot be contaminated from the main part of the manifold.

Optionally, a further passageway 23 is provided having connection means 24 to enable an air purge of the equipment to take place before a procedure is started. The passageway 23 is fitted with a conventional three-way stopcock 25 which normally isolates the passageway 23 from the main passageway 11 as diagrammatically illustrated in Figure 1 of the drawings.

In use, the pressure monitoring passageway 17 is normally open.

A pressure responsive diverter valve 26 is positioned adjacent the mouth of the pressure monitoring passageway 17. In a normal mode of the diverter valve 26, the valve member closes the passageway 11, blocking off the distal part, but allowing free communication between the pressure monitoring passageway 17 and the proximal end 14 of the manifold. Thus blood pressure monitoring takes place continuously while the diverter valve is in normal mode. The valve 26 will be effective to prevent back flow into the distal portion of the main passageway.

An optional non-return valve is provided at 22, within the main passageway 11 between the side passageways 17 and 19. This again prevents back flow of contrast medium which has been injected.

The pressure in the blood vessel can be monitored and flow is prevented through the non-return valve 22 into the remainder of the central passageway 11.

In order to inject a contrast medium, it is only necessary to operate the syringe 16 to draw fluid through the passageway 19 and through the one-way valve 21 into the main passageway 11. Because of the non-return action of the diverter valve 26 (and optionally the non-return valve 22), fluid cannot be drawn back from the main passageway 11 or pressure monitoring passageway.

Pressure then applied on the syringe 16 cannot force the contrast medium back through the non-return valve 21 so it passes along the passageway 11 (and through the non-return valve 22 if provided) and hence to the blood vessel. However injection of contrast medium from the syringe 16 increases the pressure at the distal end of the manifold and automatically operates the pressure sensitive diverter valve 26 to close the blood pressure monitoring passageway 17 and to place the two ends of the main passageway 11 in communication.

This prevents contrast medium from passing into the pressure monitoring passageway and ensures that all the contrast medium is injected into the blood vessel. The pressure monitoring apparatus cannot suffer long-term damage due to access by the contrast medium and none of the contrast medium is wasted.

As soon as pressure ceases to be exerted on the syringe 16 to inject the contrast medium, the diverter valve 26 is no longer forced into a position to close the passageway 17 and returns under its own biasing to close the distal part of the main passageway 11. The blood pressure monitoring passageway 17 therefore automatically returns to normal operation and this reduces the risk to the patient that a change in pressure in the blood vessel might be missed as a result of failure to reopen the pressure monitoring line.

Figures 2 and 3 show alternative forms of pressure responsive diverter valve. In Figure 2, a flap valve is provided comprising a soft elastomeric cushion 27 having a surrounding resilient flange 28 which normally makes sealing engagement with the wall of the main passageway 11, permitting communication between the blood pressure monitoring passageway 17 and the proximal end 14 of the passageway 11. Intake of contrast medium through the side passageway 19 using the syringe causes the cushion 27 to seat more firmly over the main passageway 11 and subsequent injection by the syringe raises the pressure at the distal end 15 and pushes the cushion of the flap valve to the dotted line position shown in Figure 2, in which it closes the blood pressure monitoring passageway 17 and allows free communication between the distal end 15 and proximal end 14 of the main passageway 11. Once injection pressure ceases, the resilience of the flange 28 forces the cushion 27 back into its normal position.

Figure 3 shows an alternative form of valve using a light-weight ball 29 which normally seats at 30 so as to close the main passageway 11. The ball 29 is held in this position by

the perforated diaphragm 31 which covers an alternative seat 32. In this case, the alternative seat 32 is provided in the straight ahead position which is now the position of the blood pressure monitoring passageway 17. The side branch from the straight ahead position is the continuation of the main passageway 11 of the manifold and leads to the proximal end 14. Other forms of geometry may however be possible.

When the pressure rises at the distal end 15 of the manifold due to injection of contrast medium, the ball 29 moves to the chain dotted position, in the alternative seat 32, blocking off the pressure monitoring passageway 17 as before and permitting flow to the proximal end 14 so that the contrast medium is injected into the blood vessel.

When injection ceases and the pressure drops at the distal end 15 of the passageway 11, the resilient perforated diaphragm 31 pushes the ball valve 29 into the seat 30, isolating the distal end 15 and reopening the communication between the main passageway 11 leading to the blood vessel and the pressure monitoring passageway 17.

It will be seen that the operation of the valves 21, 26 and 22 is fully automatic and needs no manual intervention by an operator. Thus, the operator still has a free hand available during the injection of contrast fluid.

This invention facilitates remote operation of mechanically operated syringes for contrast injections. The advantage of this is to allow the operator to be at a distance from the radiation area during angiographic imaging. Currently the need to switch the manifold valves manually necessitates the operator to be within reach of the injection lines.

Although an embodiment of the invention has been described in relation to use in angiograms, it will be appreciated that manifolds of a similar type may be used for other procedures.

In this case, further or alternative non-return valves may need to be provided in the main passageway and/or in one or more side passageways.

CLAIMS

1. A manifold for use in vascular investigations comprising a first passageway adapted to make connection with a blood vessel and a plurality of further passageways which are placed in communication with, or isolated from the first passageway under the control of at least one pressure responsive non-return valve.

2. A manifold according to claim 1 wherein the pressure responsive non-return valve comprises a pressure responsive diverter valve having a normal mode and a diversion mode selectively produced in response to a pressure rise in one of said further passageways, the diversion mode causing said one further passageway to communicate with the first passageway and simultaneously to isolate another of the further passageways; return to the normal mode reconnecting said other further passageway and isolating said first further passageway from the first passageway.

3. A manifold according to claim 2 wherein the pressure responsive diverter valve comprises a ball valve moveable between two alternative seats and normally biased into one of said seats.

4. A manifold according to claim 3 wherein the biasing is provided by a perforated membrane obstructing one of said seats.

5. A manifold according to claim 3 wherein the diverter valve comprises a flap valve having two alternative seats and resiliently biased into one of said seats.

6. A manifold according to claim 1 and using a pair of non-return valves, wherein the first passageway is a main passageway having opposite end connections, one of which is adapted to make connection with a blood vessel and also

comprising two further passageways, a distal one of which includes one of the pressure responsive non-return valves to prevent back flow into the distal passageway, a further one of the non-return valves being disposed in the main passageway between the proximal and distal secondary side passageways to prevent back flow from the proximal to the distal end of the manifold.

7. A manifold according to claim 6 wherein a further secondary side passageway is provided between the proximal passageway and the distal end of the manifold, the further passageway having a stop cock to permit purging of the manifold before commencement of a procedure.

8. A manifold substantially as hereinbefore described with reference to and as illustrated in Figures 1 and 2 of the accompanying drawings.

9. A manifold substantially as hereinbefore described with reference to and as illustrated in Figures 1 and 2 of the accompanying drawings as modified by Figure 3.

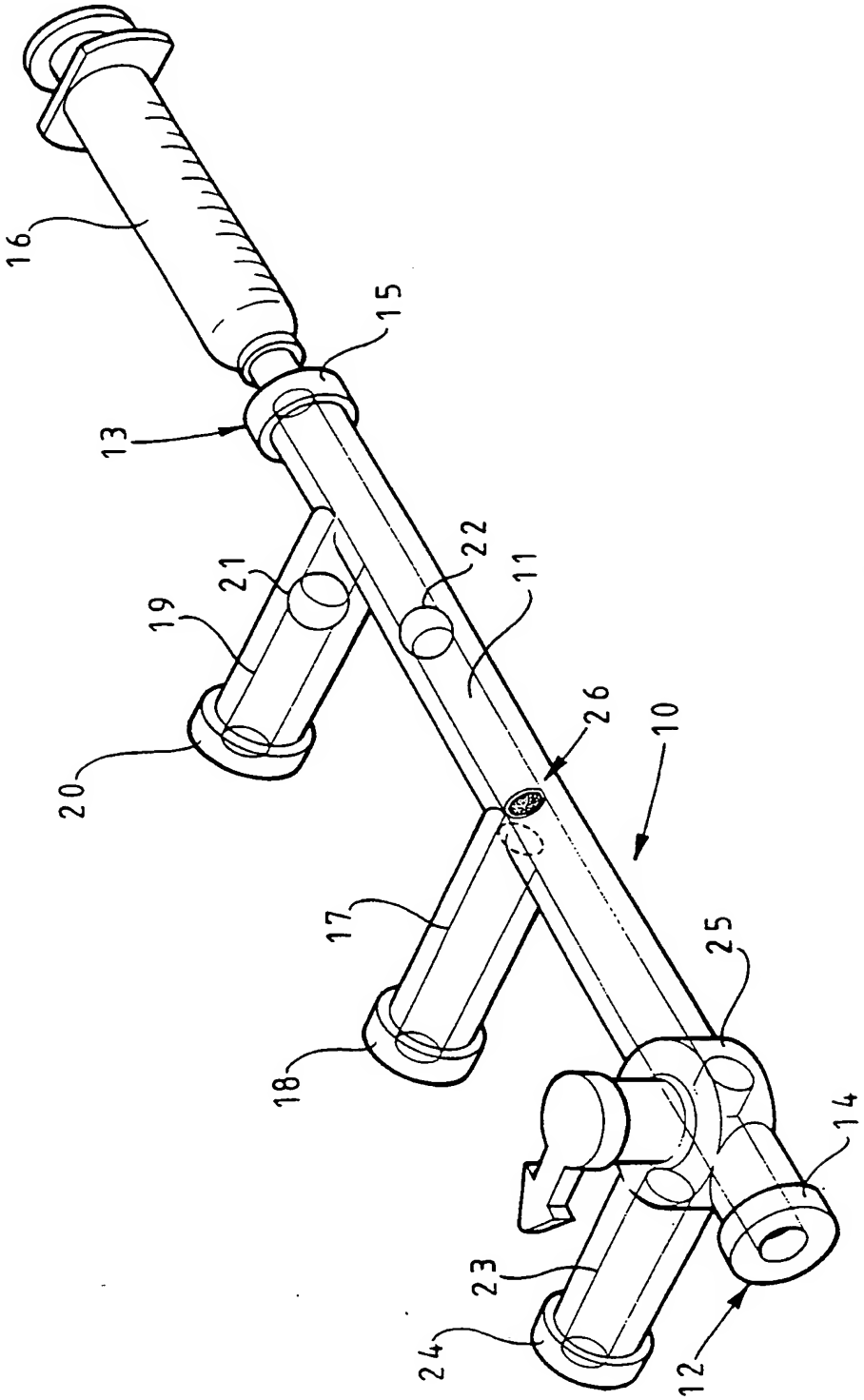


FIG 1

FIG 2

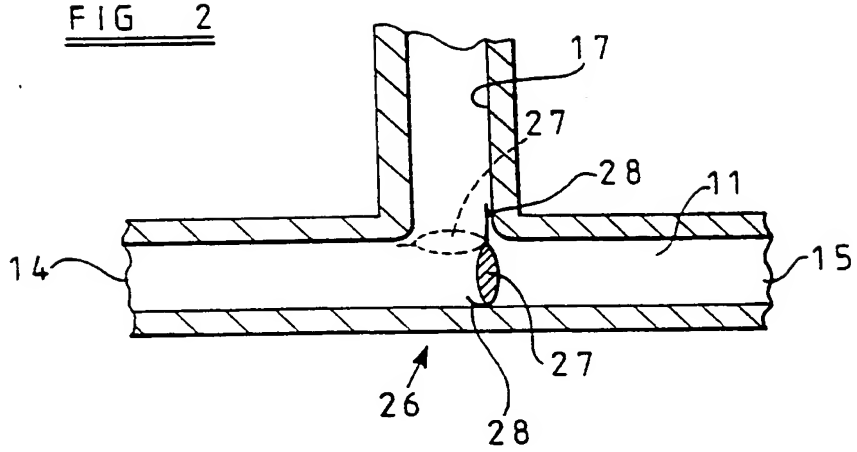
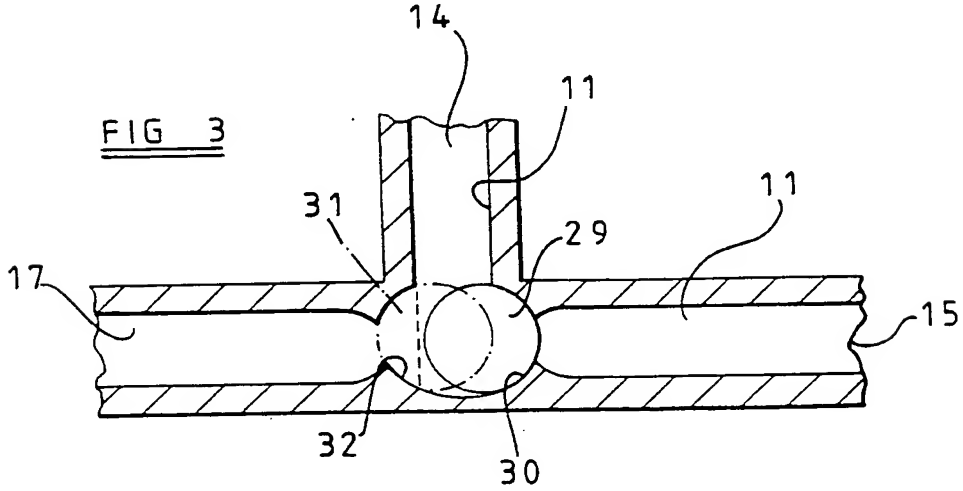


FIG 3



INTERNATIONAL SEARCH REPORT

Intern. al Application No
PCT/GB 94/00034

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61M39/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	---	2,5,6
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	EP,A,0 337 617 (WALLACE) 18 October 1989 see the whole document	

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[X] Further documents are listed in the continuation of box C.

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